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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,142

10/17/2003

William J. Curatolo

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06/12/2006

EXAMINER

PESELEV, ELLI

PFIZER INC.

PATENT DEPARTMENT, MS8260-1611

EASTERN POINT ROAD

GROTON, CT 06340

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,142	CURATOLO ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "having approximately 10% ethylene oxide by weight and having an average molecular weight of the propylene oxide block of approximately 1800" is not disclosed or suggested by the specification as originally filed.

Applicant's arguments filed May 4, 2006 have been fully considered but they are not persuasive.

Applicant contends that the term "pluronic L61" and the term "poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800" have been used interchangeably by BASF, manufacturer of Pluronic L61 and by Sigma-Aldrich. This argument has been considered but has not been found persuasive. Note that the document by Sigma-Aldrich provided by applicant describes Pluronic61 as "poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol)-block-poly(propylene glycol). There is no mention in the documents provided of the terminology "having approximately 10% ethylene oxide by weight and having an average molecular weight of the propylene oxide block of approximately 1800).

Claims 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al (U.S. Patent No. 5,605,889) in combination with the International Patent WO 99/39731 for the reasons set forth in the Office Action of January 30, 2006.

Applicant's arguments filed May 4, 2006 have been fully considered but they are not persuasive.

Applicant contends that erythromycin is not azithromycin. Applicant has also submitted a Declaration which states that azithromycin is quite different from other types of antibiotics, including erythromycin and is 326 times more stable than erythromycin. This argument and the declaration have been considered but have not been found persuasive. The International Patent discloses that Pluronic L61 is effective in enhancing the potency of a large number of biological agents (page 17). On page 36, the International Patent discloses that such agents include without limitation antibacterial agents. Therefore, a person having ordinary skill in the art at the time the present invention was made would have been motivated to combine any antibacterial agent, including azithromycin, with Pluronic L61.

The declaration By Steven C. Sutton discloses that the presence of Pluronic L61 increased the beagle dog's exposure to azithromycin by 121-240%. The declaration has been considered but has not been found persuasive the test presented is limited to the oral administration of azithromycin in combination with specific amounts of Pluronic L61. The present claims are not limited to any amount of Pluronic L61, are not limited to administration of azithromycin and Pluronic L61 in the same composition and are not

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limited to oral administration i.e. the data provided is not commensurate with the scope of the claimed invention. Further, the results obtained are to be expected from the teaching by the International Patent on page 17 that Pluronic L61 is the most effective of the block copolymers. Therefore, the claimed methods are still deemed prima facie obvious over the cited prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

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